

# Jarrow FORMULAS, INC<sup>TM</sup>

Superior Nutrition and Formulation<sup>SM</sup>

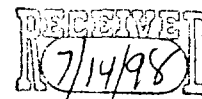
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Orders 800/890-8955  
General 310/204-2520  
Administrative 310/204-5132

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July 7, 1998

Dr. Elizabeth Yetley, Ph.D.  
F.D.A.  
Office of Special Nutrition  
200 "C" St., S.W.  
Washington, DC 20204



Please be advised that Jarrow Formulas, Inc. is marketing a product containing a "Structure and Function" statement on the label. According to the notification requirements set forth by the DSHEA (Dietary Supplement Health and Education Act, 1994) legislation, please be advised of the following:

**Name of Product:** Methyl Donors, 100 Quik-Solv<sup>TM</sup> Tablets

**Active Ingredient(s):** Trimethylglycine (Anhydrous Betaine), Vitamin B6 (Pyridoxine HCl), Vitamin B12 (Cyanocobalamin), Folic Acid, Intrinsic Factor.

**Claim(s):** "Reduces Homocysteine to Methionine." Methyl Donors is formulated with methyl group donors and supporting nutrients to facilitate methylation. Methylation is inhibited by poor dietary habits (excessive protein and fat or inadequate nutrient content), alcohol, smoking and genetic predisposition. Impairment of methylation results in elevated levels of homocysteine, a toxic amino acid and a serious health risk. Homocysteine is reduced to methionine, a biologically useful amino acid, by enzymes that require folic acid, B12, B6 and methyl groups. Intrinsic Factor facilitates the absorption of B12.

**The following disclaimer appears on the label:** These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients. A compendium of relative published research substantiating the above statement(s) is on file at the corporate office.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Siddharth S. Shastri".

Siddharth S. Shastri, B.A., C.C.N.  
Director of Product Development

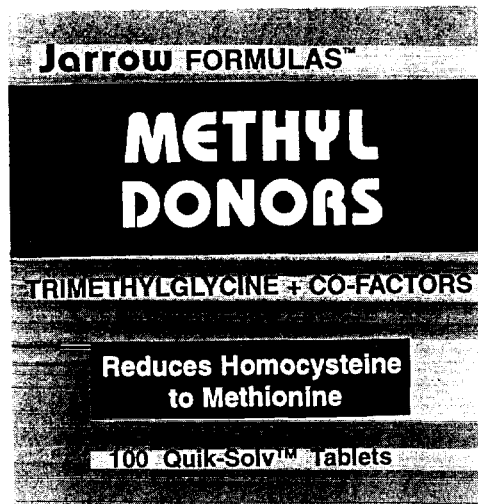
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**USAGE:** As a dietary supplement, take 1 tablet daily with a meal or as directed by your qualified health consultant.

**Methyl Donors** is formulated with methyl group donors and supporting nutrients to facilitate methylation. Methylation is inhibited by poor dietary habits (excessive protein and fat or inadequate nutrient content), alcohol, smoking and genetic predisposition. Impairment of methylation results in elevated levels of homocysteine, a toxic amino acid and a serious health risk. Homocysteine is reduced to methionine, a biologically useful amino acid, by enzymes that require folic acid, B12, B6 and methyl groups. Intrinsic factor facilitates the absorption of B12.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



Each **Methyl Donors** Quik-Solv™ tablet contains:

	AMOUNT	% RDI
Trimethylglycine (TMG) (Anhydrous Betaine)	500 mg	*
Vitamin B6 (Pyridoxine HCl)	15 mg	750%
Vitamin B12 (Cyanocobalamin)	250 mcg	4167%
Folic Acid	400 mcg	100%
Intrinsic Factor	10 mg	*

RDI for humans 12 years of age and older.  
\* Need in human nutrition not established.

Contains NO allergen or sugar.  
Quik-Solv™ tablets disintegrate within minutes of ingestion.

Superior Nutrition and Formulation™ by  
**Jarrow FORMULAS, INC™**  
Los Angeles, CA 90035-4317

PROD # 20006

Lot #: Best Used Before:

